



DEPARTMENT OF HEALTH & HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION

630  
PHILADELPHIA DISTRICT

WARNING LETTER

900 U.S. Customhouse  
2nd and Chestnut Streets  
Philadelphia, PA 19106

Telephone: 215-597-4390

July 15, 1997

97-PHI-33

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Luke A. Marano Jr., President  
Conte Luna Foods  
910 E. Main Street  
Norristown, PA 19401

GEN.	SPEC.
RELEASE	
F#	7/16/97
Reviewed by: <i>[Signature]</i>	

Dear Mr. Marano:

The Food and Drug Administration has reviewed labels collected during an inspection of Conte Luna Foods, 910 E. Main St., Norristown, PA., conducted on January 22 and 23, 1997. Based on our review of the labels for Ringlets, Enriched Neapolitan Egg Products, Curly Medium, Enriched Neapolitan Egg Noodles, and Rotini No. 51 a Macaroni Product, we have determined that these products are misbranded under Section 403 of the Food, Drug, and Cosmetic Act (the Act) and Title 21 Code of Federal Regulations (CFR) as follows:

RINGLETS, ENRICHED NEAPOLITAN EGG PRODUCTS

The product is misbranded within the meaning of section 403(r)(2)(B) of the Act in that the label bears the statement "A Very Low Sodium Food," which is a nutrient content claim under 21 CFR 101.61(b)(2), and the labeled cholesterol content per serving is 70 mg, which exceeds the disclosure level for cholesterol under 21 CFR 101.13(h)(1); however the label fails to disclose information about cholesterol, as required by 21 CFR 101.13(h), i.e., "See (appropriate panel) for information about cholesterol and other nutrients."

The label of the product fails to bear an appropriate identity statement. This product purports to be a type of noodle product which is subject to an established standard of identity. However, the label fails to identify the product by one of the names set forth in the appropriate standard of identity. For your information, there are two standards of identity for noodle products: 21 CFR 139.150 (noodle products), and 21 CFR 139.155 (enriched noodle products). Under the standards, the product may be identified as "Ringlets Noodle Product," or "Ringlets Egg

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Noodle Products," or as "Enriched Ringlets Noodle Product" or "Enriched Ringlets Egg Noodle Product" depending on which standard of identity applies to your product. However, the product must meet the compositional as well as labeling requirements set forth by the appropriate standard. It is unclear to us which standard you intend to follow.

We note that the label includes the term "enriched" as part of the product's name. If you intend to market an "enriched" noodle product, be aware that the levels of thiamine, riboflavin, niacin or niacinamide, and iron as declared on the label fall below the minimum levels required by the "Enriched Noodle Product" standard of identity. Consequently, you would have to add additional quantities of the nutrients to comply with the standard. The use of "enriched flour" alone may not be sufficient to meet the standards for enriched noodles.

CURLY MEDIUM, ENRICHED NEAPOLITAN EGG NOODLES

The product is misbranded within the meaning of section 403(r)(2)(B) of the Act in that the label bears the statement "A Very Low Sodium Food" which is a nutrient content claim under 21 CFR 101.61(b)(2); however the label fails to bear the referral statement as required by 21 CFR 101.13(g), i.e., "See \_\_\_\_\_ for nutrition information" (with the blank being filled in with the identity of the panel on which the nutrition information is located)." Be advised that if the level of cholesterol is more than 60 mg per reference amount and per labeled serving size, the referral statement must include cholesterol disclosure.

ROTINI No. 51, A MACARONI PRODUCT

The product is misbranded within the meaning of section 403(r)(2)(B) of the Act in that the label bears the statement "Salt Free," but fails to bear the referral statement as required by 21 CFR 101.13(g), i.e., "See \_\_\_\_\_ for nutrition information" (with the blank being filled in with the identity of the panel on which the nutrition information is located)."

The law requires that the net contents be declared in metric units as well as inch-pound units. However, FDA has not published final regulations on how the declaration is to be made. We recommend that if you wish to avoid having to change labels again when the regulations on the metric declaration become effective, you should add metric contents statements now, using the guidance provided in the proposed regulations published in the FEDERAL REGISTER of December

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21, 1993. We expect that any differences between that proposal and the final regulations will be minor and will not by themselves require a label change.

We also have the following additional comments regarding the labeling of the above-referenced products:

RINGLETS, ENRICHED NEAPOLITAN EGG PRODUCTS and CURLY MEDIUM, ENRICHED NEAPOLITAN EGG NOODLES

The listing of ingredients should not be enclosed within the box that contains the nutrition labeling.

RINGLETS, ENRICHED NEAPOLITAN EGG PRODUCTS and CURLY MEDIUM, ENRICHED NEAPOLITAN EGG NOODLES and ROTINI No. 51, A MACARONI PRODUCT

The serving size fails to be expressed in terms of common household measure, i.e., in terms of cups, tablespoons, or teaspoons, (e.g., "\_\_\_cup(\_\_\_g)") (21 CFR 101.9(b)(5)(i)).

This is not meant to be all-inclusive listing of all the deficiencies found in your food product labels. It is your responsibility to ensure that all your products are labeled in compliance with the Food, Drug, and Cosmetic Act. You should take prompt action to bring your labeling into compliance with current regulations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter of the specific steps you have taken. If available, copies of proposed or revised labels should be submitted with your response. Also provide analytical information regarding the amount of cholesterol in "CURLY MEDIUM, ENRICHED NEAPOLITAN EGG NOODLES". If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which the correction will be completed. Your reply should be directed to James C. Illuminati, Compliance Officer, at the address shown above.

Sincerely,



Diana J. Kolaitis  
District Director  
Philadelphia District

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cc: Jennifer Payton, QC Manager  
Conte Luna Foods  
910 E. Main St.  
Norristown, PA. 19401

cc: Pennsylvania State Department of Agriculture  
Bureau of Foods and Chemistry  
2301 North Cameron Street  
Harrisburg, PA 17120-9408  
Attn: Division of Food Control  
Leroy C. Corbin, Director